

increased by the IgM and IgA immunoglobulins to [substantially prevent] inhibit adherence of the immunogen in the intestinal tracts of the animals thereby promoting the growth of the animals.

Cancel Claim 10, 11, 25 and 26 without prejudice.

REMARKS

Reconsideration of this application, as amended, is requested.

Claims 10, 11, 25 and 26 have been cancelled. The rejection of these claims under 35 USC 112 set out in pages 3 to 7 of the Office action and the rejection of Claims 10 and 25 under 35 USC 102(b) are moot.

The specification including the claims define methods of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony forming protein wasting immunogen in the rumen or intestinal tracts of the animals. The method inhibits the ability of the target protein wasting immunogen from adhering to the rumen or intestinal tract of the animals. This reduces the ability of the protein wasting immunogen to multiply in the rumen and digestive tract of the animal. The available protein is not reduced by the immunogen whereby more protein is utilized by the animals to promote growth. The increase in dietary protein in vivo results in feed efficiency and increases in growth of the animals. The control of growth of this organism in the animal boosts feed efficiency and promotes growth of the animal. *Specification, page 7, lines 3 to 17.* The target protein wasting immunogen is from a class consisting of *P.anaerobius*, *C.sticklandii* and *C.aminophilium*. These immunogens are described in Examples 7, 8 and 9 on pages 17 and 18 of the specification. Examples 17, 18 and 19 relate to these immunogens. *Specification, pages 23 and 24.*

Organisms that colonize in the rumen and digestive tract of a host animal must possess

the capability of sticking or adhering to the rumen or intestinal tract surface in order to multiply and grow. *Specification, page 9, lines 15, 16.* The organism inhibitor of the invention interferes with adherence in a highly specific manner and on a cumulative basis prevent the targeted organism from multiplying, growing and colonizing. *Specification, page 9, lines 20-22.*

Immunized hens layer unique IgY type immunoglobulins in the yolk of the egg and deposit IgM and IgA immunoglobulins in the albumin. *Specification, page 10, lines 21-23.* The albumin containing the IgM and IgA immunoglobulins helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification, page 11, line 1.* The organism inhibitor is the colonizing microorganism adhesion inhibitor that is an avian antibody, IgY immunoglobulins, which can very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Specification, page 10, lines 8-10.* The albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is that use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animal.

The examiner's objection to the terms "yolk and albumin" is noted. The whole or entire egg excluding the shell comprises the yolk and albumin. The claimed method utilizes the entire contents of the eggs separated from the shells. The yolks are not separated from the albumin. The whole egg contents includes IgY type immunoglobulins in the yolk and IgM and IgA

immunoglobulins in the albumin as disclosed on page 10, lines 21 to 23 and page 11, line 1 of the specification. The whole egg is disclosed in Examples 11, 19, 21, 23 24 and 27. Claims 14, 15, 16, 27, 29 and 31 have been amended to change "yolk and albumin" to --entire contents of the eggs-- separated from the shells. The terms "substantially prevent" have been replaced with --inhibit--. This amendment overcomes the rejection of the claims under 35 USC 112 as set out in pages 7 and 8 of the Office action.

Claims 14, 15, 16, 27, 29 and 31 have been amended to more particularly define applicants' method of promoting growth in food animals. These claims define the utility of albumin IgM and IgA immunoglobulins to increase the binding in the mucus tissue of the digestive tract of the animal of the antibody containing whole egg to provide a longer sustaining effect of the antibody. It is noted by the examiner that *Tokoro et al* does not teach the use of albumin IgM and IgA in conjunction with yolk IgY to inhibit adherence targeted immunogens in the intestinal tract of an animal.

Tokoro et al discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolk of the eggs. The yolk is separated from the albumin. The yolk is homogenized and dried to form a powder. The powder administered to the animal by the oral route is useful for the prevention and treatment of colibacillosis and diarrhea in animals. *Tokoro et al* does not teach the use of albumin IgM and IgA in conjunction with yolk IgY to inhibit adherence of targeted immunogens in the intestinal tract of an animal thereby inhibiting colony growth of the targeted immunogen and promoting growth of the food animal.

Krause et al discloses that amino acid degradation in the rumen of animals is nutritionally wasteful and produces more ammonia than the bacteria in the rumen can utilize. The excess ammonia is converted by the animal into urea and discharged into the environment as environmental pollution. The feed additive monensin decreases ammonia accumulation in the

rumen. *Krause et al* discovered that monensin inhibited growth of *P.anaerobius* and *C.sticklandii* in the rumen of an animal but did not inhibit *C.aminophilium*. The result was the reduction in the amount of ammonia in the rumen and reduction of environmental pollution. There is no teaching that monensin prevents adherence of a targeted immunogen in the intestinal tract of an animal thereby inhibiting its colony growth. Monensin does not promote the growth of food animals by preventing targeted immunogens from adhering to the intestinal tract of an animal.

It is clear that applicants' claimed method of promoting the growth of food animals is not obvious from the teachings of *Krause et al* and *Tokoro et al*. There are no motivating directions in these references that would impel one skilled in the art to do the claimed method. Applicants request that the examiner reconsider the teachings of *Tokoro et al* and *Krause et al* and withdraw the rejection of the claims based on these references.

Claims 17 to 24 and 27 to 32 include the process of providing a dry feed carrier material. The carrier material is coated with the entire contents of the eggs separated from the shells. The dry feed carrier material absorbs moisture from the entire contents of the eggs thereby drying the entire contents of the eggs, yolk and albumin, on the carrier material. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard feeds. *Example 21, page 24*. The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The yolk IgY immunoglobulins bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the protein-wasting immunogen in the intestinal tract of the animal. The albumin IgM and IgA increases this binding action.

Claims 17 to 32 have been rejected under 35 USC 103(a) as unpatentable over *Krause et*

al and *Tokoro et al* as applied to Claims 10 to 11 and 14 to 16 and further in view of *Betz et al* and *Adalsteinsson et al*. The amendments and remarks concerning Claims 14 to 16 are applicable to Claims 17 to 24 and 27 to 32. *Betz et al* and *Adalsteinsson et al* do not add to the teachings of *Krause et al* and *Tokoro et al*. Reconsideration of this rejection is requested.

Adalsteinsson et al does not teach coating a dry feed carrier with the entire contents of eggs separated from shells to dry the entire contents of the eggs. Additional drying methods are not used to further dry the entire contents of the eggs. Dried egg powder mixed with animal feed rations does not dry the egg powder. Also, spraying dried egg powder on food pellets in oil does not dry the egg powder.

Betz et al does not disclose drying of the entire contents of eggs separated from the shells with soybean hulls, rice hulls or cottonseed hulls. The *Betz et al* animal feed is a mixture of materials including three hulls coated with a vegetable oil. The hulls are not used to dry any feed materials.

In view of the absence of a teaching by *Betz et al* and *Adalsteinsson et al* of the claimed drying of the entire contents of eggs separated from the shells with a dry feed carrier material, it would not have been obvious to a person skilled in the art to make and use the method defined in Claims 17 to 24 and 27 to 32.

Clean copies of the amended claims are enclosed.

In view of the above remarks and amended claims, applicants request allowance of Claims 14 to 24 and 27 to 32.

Respectfully submitted,

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